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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,690	07/21/2006	Shalom Z. Hirschman	1641/4/2/3 PCT/US	1557

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EXAMINER
HARRIS, ALANA M

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,690	HIRSCHMAN, SHALOM Z.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-24) in the reply filed on April 28, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-27 are pending.

Claims 25-27, drawn to non-elected inventions are withdrawn from examination.

Claims 1-24 are examined on the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Doctor's Guide article, Clinical Results of RETICULOSE in Patients With AIDS (December 10, 1996). The article teaches the administration of RETICULOSE® also known as Product R to patients with AIDS, see first paragraph on page 1. This treatment provided an increase in T-cell lymphocytes, see fifth paragraph of page 1. These results intrinsically provide maintaining and improving production of white blood

cells. The article does not teach a method of maintaining and improving production of white blood cells *in a cancer patient undergoing chemotherapeutic treatments in the recited dosages* presented in Applicant's claims 2-4.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to treat the cancer patient population undergoing chemotherapeutic treatments with Product R. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art and the article that effective treatment of HIV involves the improvement and augmentation of the T cell population, which are white blood cells. As provided by the results maintaining and improving production of white blood cells was achieved.

It also would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer Product R in recited dosages and time points established in Applicant's claims. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that the dosages of any therapeutic agent must be adjusted and optimized.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinnici, M.D. (Plata Partners Limited Partnership, July 6, 1992). Dr. Chinnici teaches the administration of RETICULOSE® also known as Product R to patients with AIDS, see first paragraph on page 3, last paragraph; page 4, Methodology section. This treatment provided an increase in T-cell lymphocytes, see second, third and fifth

paragraph of page 5; Results chart of page 6. These results intrinsically provide maintaining and improving production of white blood cells. The article does not teach a method of maintaining and improving production of white blood cells *in a cancer patient undergoing chemotherapeutic treatments in the recited dosages* presented in Applicant's claims 2-4.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to treat the cancer patient population undergoing chemotherapeutic treatments with Product R. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art and the article that effective treatment of HIV involves the improvement and augmentation of the T cell population, which are white blood cells. As provided by the results maintaining and improving production of white blood cells was achieved.

It also would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer Product R in recited dosages and time points established in Applicant's claims. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that the dosages of any therapeutic agent must be adjusted and optimized.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 13-16 of U.S. Patent No. 5,807,839 (issued September 15, 1998), in view of U.S. Patent 7,067,139 (filed May 21, 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to the same/similar method of treating a patient suffering from a blood disorder resulting from chemotherapy with the parenteral administration of an effective treatment amount of Product R in a sterile injectable formulation. While the patients of the patent suffer from anemia resulting from chemotherapy, whereas the instantly claimed invention recites cancer patients undergoing chemotherapy, one of ordinary skill in the art would readily envisage cancer patients undergoing chemotherapy since that particular form of treatment is conventional in the art as set forth in the instant application, see pages 2 and 3. While the patent's claimed methods are silent with respect to maintaining and increasing production of platelets in the blood or reducing gastric-intestinal toxicity as the recited

intended benefits of the instant claimed methods. It also would have been *prima facie* obvious to one of ordinary skill in the art to administer Product R in a manner that was not subcutaneous, intralesional, topical or by injection because patent '139 teaches oral administration of Product R, see column 3, lines 39-43. It would have been *prima facie* obvious to one of ordinary skill in the art to implement the method steps of the two patient populations undergoing chemotherapy would be treated by the same manipulative steps with the same or overlapping effective amounts of the same Product R as claimed, thus the intended benefits recited in the instantly claimed method must necessarily flow from the method rendered obvious be the patented claims.

8. Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-12 of copending Application No. 10/456,668 (filed June 5, 2003), in view of U.S. Patent 7,067,139 (filed May 21, 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same/similar method of treating a patient suffering from a blood disorder resulting from chemotherapy with the parenteral administration of an effective treatment amount of Product R in a sterile injectable formulation. While the patients of the instant application suffers from a reduction in white blood cells resulting from chemotherapy, whereas the copending claimed invention recites cancer patients with reduced number of platelets and gastric-intestinal toxicity undergoing chemotherapy (as does the copending application), one of ordinary skill in the art would readily envisage cancer patients

undergoing chemotherapy since that particular form of treatment is conventional in the art as set forth in the instant application, see pages 2 and 3. It would have been *prima facie* obvious to one of ordinary skill in the art to implement the method steps of the three patient populations undergoing chemotherapy would be treated by the same manipulative steps with the same or overlapping effective amounts of the same Product R as claimed, thus the intended benefits recited in the instantly claimed method must necessarily flow from the method rendered obvious be the patented claims. It also would have been *prima facie* obvious to one of ordinary skill in the art to administer Product R in a manner that was not subcutaneous, intralesional, topical or by injection because patent '139 teaches the oral administration of Product R, see column 3, lines 39-43.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
23 June 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643